



Food and Drug Administration
10903 New Hampshire Avenue
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BioStructures, LLC
% Patsy J. Trisler, JD, RAC
Regulatory Consultant
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5600 Wisconsin Avenue, #509
Chevy Chase, Maryland 20815

January 16, 2015

Re: K142276
Trade/Device Name: MCS Bone Graft
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: December 8, 2014
Received: December 9, 2014

Dear Ms. Trisler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142276

Device Name: MCS Bone Graft

Indications for Use:

MCS Bone Graft is a bone void filler device intended for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. MCS Bone Graft is indicated to be packed gently into bony voids or gaps of the skeletal system (i.e., extremities and pelvis) and is used mixed with bone marrow aspirate. Once implanted, the device resorbs and is replaced with host bone during the healing process.

Type of Use (Select one or both, as applicable)

<input checked="" type="checkbox"/> Prescription Use (Part 21 CFR 801 Subpart D)	<input type="checkbox"/> Over-The-Counter Use (21 CFR 801 Subpart C)
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Section 5 510(k) Summary

Submitter Name: BioStructures, LLC

Submitter Address: 1201 Dove Street, Suite 470
Newport Beach, CA 92660

Contact Person: John Brunelle, Ph.D.
Chief Technology Officer

Phone Number: 949.553.1717

Date Prepared: August 14, 2014

Device Trade Name: MCS Bone Graft

Common Name: Bone void filler

Classification Name: Resorbable Calcium Salt Bone Void Filler Device

Classification Number: 21 CFR 888.3045

Product Code: MQV

Device Class: 2

Predicate Device(s): K032288, Vitoss® Scaffold Foam Pack, Stryker/Orthovita
K051774, MBCP™, Biomatlante

Indications for Use Statement: MCS Bone Graft is a bone void filler device intended for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. MCS Bone Graft is indicated to be packed gently into bony voids or gaps of the skeletal system (i.e., extremities and pelvis) and is used mixed with bone marrow aspirate. Once implanted, the device resorbs and is replaced with host bone during the healing process.

Device Description: Device Identification and Materials of Use:
MCS Bone Graft is a resorbable bone void filler device comprised of biphasic mineral granulate suspended in a porous type I collagen matrix.

Device Characteristics:
The implant is designed to be hydrated with bone marrow aspirate prior to implantation to facilitate handling and placement in bony defects. The device is supplied freeze dried in strip form, and packaged in a sterile barrier foil pouch. The device is provided sterile, for single use, in a variety of sizes.

Body Contact:
The device is a permanent resorbable implant in bone tissue.

Mechanism of Action:

The device's composition allows for resorption and remodeling over time. It is an osteoconductive scaffold for new bone regeneration.

Environment of Use:

The device is for use only in a health care facility/hospital.

Summary of Testing: Non-clinical testing was performed in accordance with FDA recognized consensus standards and FDA guidance documents as applicable.

Raw materials characterization testing was performed according to ASTM standards: F1185-03, F1088-04a, F2212-11.

Biocompatibility testing, according to ISO 10993 for a long-term implant product, demonstrated the device is biocompatible and non-toxic.

Packaging, sterilization and shelf life testing according to the following standards are presented in the 510(k):

- Packaging: ISO 11607, ASTM F2096-11 & F88-09, and ISO 11137.
- Sterilization and Shelf Life; ISO 11137 and ASTM F1980.

Animal performance testing was performed in a femoral cancellous defect rabbit model to evaluate the safety and performance of the MCS Bone Graft compared to a predicate device. The test results showed equivalent in vivo performance in safety, graft resorption and new bone formation.

Comparison to the Predicate Devices: MCS Bone Graft has the same intended use and the same principles of operation as all the predicates, which serve as osteoconductive scaffolds for new bone formation.

MCS Bone Graft is similar technologically to the two predicates.

The technological differences presented by the composition of materials in MCS Bone Graft do not raise new issues of safety or effectiveness, as demonstrated by the side-by-side evaluation in the animal performance studies.

Substantial Equivalence Conclusion: The comparisons and study data presented in the 510(k) lead to the conclusion that MCS Bone Graft is substantially equivalent to the predicate devices.